K130344

MAR 2 1 2013

510(k) SUMMARY
Medilas H Uropulse

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Dornier MedTech America
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Kennesaw, GA 30144

Phone: 770-514-6163
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Date Prepared: February 21, 2013

Contact Person: John Hoffer

Phone: 770-514-6163

Name of Device and Name/Address of Sponsor
Medilas H Uropulse
1155 Roberts Blvd.
Kennesaw, GA 30144

Common or Usual Name
Holmium: Yttrium Aluminum Garnet (HO:YAG) Laser System

Classification Name
The General and Plastic Surgery Branch has classified Surgical Powered Laser Instruments (Product Code GEX) as a Class II device pursuant to 21 C.F.R. § 878.4810.

Predicate Devices
Dornier Medilas H Solvo K122159
Dornier Medilas H20 Laser K061455
Versa Pulse P20 (K100228)

Purpose of the Special 510(k) Notice
The Uropulse is a modification to the Dornier Medilas H Solvo Laser (K122159).

Device Description
The Dornier Medilas D Uropulse Laser is a solid-state Holmium YAG Laser. The laser emits laser radiation in the invisible wavelength range of 2080 nm in either a continuous-wave or pulsed mode, which is absorbed primarily by water, with an average penetration depth of approximately 400µm (0.4mm). Due to the application-dependent optimization of the pulse time of 350 microseconds, the Uropulse can be used in various medical applications including breaking up stones, cutting tissue, tissue ablation, coagulation and vaporization.

The laser is microprocessor-controlled utilizing a watchdog-monitored microprocessor and operates with an internal cooling system and a heat exchanger. The bottom of the housing serves as a tank for cooling water and, at the same time, a base for the laser unit. A cooling circuit conducts away heat that is generated by the laser pump lamp. Water heated by the laser pump is conducted out of the cavity and into the stainless steel cooler. Following cooling, it is returned to the tanks.

A graphic control panel regulates and displays the operating parameters, application modes, time functions, system status and messages to the User. The control panel consists of a display with integrated touch screen panel applications to control the functions of the laser.

The laser light emission is transmitted to the application site by a sterile fiber optic delivery system (fiber cable) with a SMA 905 connector. Laser energy is transmitted through the fiber to the application site by depressing a foot pedal. The foot pedals, both the wired and wireless, are water- proof and explosion-proof. Various fiber sizes can be utilized depending on the application.

The laser pulse energy at the distal end of the fiber lies within the range of 200-3500mJ. The pulse frequency can be adjusted in 0.2Hz increments between 3 and 20 HZ. The Uropulse contains an aiming beam at a wavelength of 532nm at the maximum power aperture of 1mW. The device employs a Class IV (4) laser pursuant to 21 CFR 1040 and IEC/EN 60825-1.

Intended Use

The Uropulse is intended to be used for cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopes), or for open surgery for contact or non-contact surgery with or without a handpiece for use in incision/excision, vaporization, ablation and coagulation of soft tissue. The Uropulse is indicated for use in medicine and surgery, in the following medical specialties:

- Arthroscopy
- Urology
- Lithotripsy
- Pulmonology
- Gastroenterology
- Gynecology
- ENT
- General Surgery

Substantial Equivalence

From a clinical perspective and comparing design specifications, the Uropulse and the predicate devices are substantially equivalent and have the same intended use. Based on the technological characteristics, design and overall performance of the devices, Dornier MedTech America believes that no significant differences exist between the Uropulse and the Dornier Medilas H Solvo Laser (K122159).

Dornier MedTech America, Inc. believes the minor differences do not raise any concerns regarding the overall safety or effectiveness. Thus, the Uropulse is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Dornier Medtech America, Incorporated
% Mr. John Hoffer
Vice President of Quality, Regulatory and Clinical
1155 Roberts Boulevard
Kennesaw, Georgia 30144

March 21, 2013

Re: K130344
Trade/Device Name: Medilas H Uropulse
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 21, 2013
Received: February 25, 2013

Dear Mr. Hoffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130344

Device Name: Medilas H Uropulse

Indications for Use:

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- Gynecology
- ENT
- General Surgery

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.03.21 09:30:10 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K130344